PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Mitsuru HASEGAWA

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Filed: December 11, 2003 Examiner: Not yet assigned

For: TRANSFER NEEDLE ASSEMBLY

TRANSMITTAL OF ENGLISH LANGUAGE TRANSLATION OF PRIORITY APPLICATION & STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

December 11, 2003

Sir:

Applicant submits herewith an English language translation of the Japanese priority application, Japanese Patent Application No. 2002-367640, for the United States patent application identified above, with a statement that the translation is accurate. A claim to priority is filed concurrently herewith.

In the event any fees are required, please charge our Deposit Account No. 111833.

Respectfully submitted,

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STATEMENT

I, Ryohei NAMBA, hereby sate that I am competent in both the Japanese and English languages and that the attached English language document is an accurate translation of Japanese Patent Application No. 2002-367640.

Date : December 8, 2003

Signature : Ryohei Namba

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[Name of the Document] PATENT APPLICATION

[Reference No.] 14-094

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[Notification of Fee]

[Deposit List No.] 003919

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[List of Documents Attached]

[Name of Document] Specification 1

[Name of Document] Drawings 1

[Name of Document] Abstract 1

[Request of Proof] Yes

[Name of the Document] Specification

[Title of the Invention] Transfer needle assembly

[Scope of Claims]

[Claim 1] A transfer needle assembly comprising:

a cap-like outside guide member having a top surface and a skirt portion;

a tubular inside guide member that is inserted into the outside guide member; and

a puncture member provided so as to pass through the top surface of the outside guide member,

wherein:

the puncture member is a tubular member having at its proximal end a tip fitting portion for fitting a syringe tip and having a puncture needle at its distal end;

the puncture needle is provided with a gas passage and a liquid passage;

the liquid passage communicates with the tip insertion portion;

the gas passage is open to an outside portion through an air filter;

the inside guide member is capable of sliding from a position where a distal end of the puncture needle recedes into an inside of the inside guide member, to a position where the distal end of the puncture needle projects out to an outside of the inside guide member, along an inner wall of the skirt portion of the outside

guide member;

at the position where the distal end of the puncture needle recedes to the inside of the inside guide member, the outside guide member and the inside guide member are brought into engagement with each other so as to be incapable of sliding; and

the engagement between the outside guide member and the inside guide member is released by inserting a mouth portion of a vial into the inside guide member.

[Claim 2] A transfer needle assembly according to claim 1,

wherein the skirt portion of the outside guide member includes:

an annular projection provided in an inner wall of a distal end of the skirt portion;

a plurality of notches formed in a portion on a proximal end side with respect to the annular projection; and

a plurality of flexible engaging claws provided in the plurality of notches, the plurality of flexible engaging claws inclining toward an inside in a distal end direction,

wherein a proximal end side of the inside member includes:

an annular projection provided in an outer wall of a proximal end;

a plurality of notches formed in a proximal end portion corresponding to the plurality of engaging claws; and

a plurality of flexible pushing claws formed in the plurality of notches, the plurality of flexible pushing claws inclining toward

an inside in a proximal end direction, and

wherein, at the position where the distal end of the puncture needle recedes into the inside of the inside guide member, the engaging claws and the proximal end of the inside guide member are brought into engagement with each other and the annular projection of the outside guide member and the annular projection of the inside guide member are brought into engagement with each other, and by inserting the mouth portion of the vial into the inside guide member, the pushing claws push the engaging claws to the outside, causing the engagement claws to deform to release the engagement between the outside guide member and the inside guide member.

[Claim 3] A transfer needle assembly according to claim 1 or claim 2, wherein the puncture member is formed integrally with the outside guide member.

[Claim 4] A transfer needle assembly according to claim 1 or claim 2, comprising a puncture needle insertion portion provided on an axis of a top surface of the outside guide member and having a hole that passes through the top surface,

wherein the puncture member, which is provided separately from the outside guide member, is inserted into the hole of the puncture needle insertion portion.

[Claim 5] A transfer needle assembly according to any one of claims 1 to 4, comprising a plurality of vertical ribs provided in an inner wall of the inside guide member.

[Claim 6] A transfer needle assembly according to any one of claims 1 to 5, comprising a collar formed in the distal end of the skirt portion of the outside guide member, the collar inclining to the outside in the distal end direction.

[Detailed Description of the Invention]

[0001]

[Technical Field to which the Invention belongs]

The present invention relates to a transfer needle assembly. The transfer needle assembly of the present invention eliminates problems such as the contamination of the tip of a needle before use and an injury by the tip of a needle and the leakage of a liquid when in use.

[0002]

[Prior Art]

For the preparation of a component liquid to be applied to a living body or to be mixed and injected at a medical facility or self-injection for home medical treatment, a dried medicine contained in a vial is dissolved, prepared and then transferred to a syringe to be used. A syringe with a needle or a tool having a hollow puncture needle at both ends, called "double-ended needle", has been used for these operations. That is, when the syringe with a needle is used, a rubber stopper in the mouth portion of a solution container is pricked with the needle to collect a predetermined amount of the solution into the syringe and then a rubber stopper

in the mouth portion of a vial is pricked with the needle to inject the solution into the vial. Then the vial is shaken to dissolve the medicine and the rubber stopper is pricked with the needle again to collect a predetermined amount of the medicinal liquid into the syringe. Further, when the double-ended needle is used, the rubber stopper of a vial filled with a medicine and the rubber stopper of a solution container are pricked with the puncture needles at both ends of the double-ended needle to communicate them, the solution is transferred to the vial to dissolve the medicine, the solution container and the double-ended needle are removed from the vial, and the rubber stopper of the vial is pricked with the needle likewise to collect a predetermined amount of the medicinal liquid into the syringe.

[0003]

These prior arts involve a problem in that when the operation of dissolving a medicine is carried out using the syringe with a needle, the operation is complicated, the tip of the needle may be contaminated before use as the needle is exposed, and a patient or the like may get injured by the tip of the needle when in use. Further, when the double-ended needle is used and the needle is pulled out or a predetermined amount of the medicinal liquid is collected into the syringe, a patient or the like may get injured by the tip of the needle and the tip of the needle may be contaminated before the collection of the medicinal liquid as the tip of the

needle is exposed like the syringe with a needle. To solve the above problems, there is proposed an admixture injection adaptor which enables the injection and collection of a medicinal liquid during dissolution operation (refer to Patent Document 1, for example).

[0004]

[Patent Document 1]

Japanese laid-open publication No. JP 2002-360593 A (paragraphs [0008] to [0012], Fig. 1 and Fig. 2)

[0005]

In the admixture injection adaptor of the above Patent Document 1, a hollow puncture needle and a pipe-shaped tip fitting part are set on opposite sides on the axis of a disc hub, respectively, and on the outer edge of the hub, tubular skirts concentrically extended over the puncture needle and the tip fitting part are constructed. The adaptor is convenient when it is used to transfer a medicinal liquid in a vial to a syringe after a dried medicine in the vial is dissolved to prepare the medicinal liquid while the contamination of the tip of the needle or an injury by the needle is avoided. However, the length of the skirt is limited to prevent the end of the skirt from contacting with the shoulder of the vial when the vial is pricked with the needle, whereby the vial cannot be fitted straight, thereby forming a gap between the rubber stopper of the vial and the needle and thereby causing the leakage of the medicinal liquid during dissolution operation.

[0006]

[Problem to be solved by the Invention]

The present invention has been made in view of the above circumstances, and it is, therefore, an object of the present invention to provide a transfer needle assembly with which: the dissolution operation can be carried out easily; the contamination of the tip of the needle and an injury by the tip of the needle can be avoided; and the leakage of a liquid during the dissolution operation can be prevented.

[0007]

[Means for solving the Problems]

From results of extensive studies, the inventors of the present invention have conceived of providing a double structure to a vial guide portion in order to solve the problems described above, thus arriving at the present invention. That is, at a stage before use, a needle tip is housed in an inside vial guide portion, and the inside vial guide portion is retracted when piercing a needle tip into a rubber stopper. That is, the present invention relates to a transfer needle assembly including: a cap-like outside guide member having a top surface and a skirt portion; a tubular inside guide member that is inserted into the outside guide member; and a puncture member provided so as to pass through the top surface of the outside guide member, in which: the puncture member is a tubular member having at its proximal end a tip fitting portion for fitting a syringe

tip and having a puncture needle at its distal end; the puncture needle is provided with a gas passage and a liquid passage; the liquid passage communicates with the tip insertion portion; the gas passage is open to an outside portion through an air filter; the inside guide member is capable of sliding from a position where a distal end of the puncture needle recedes into an inside of this inside guide member, to a position where the distal end of the puncture needle projects out to an outside of the inside guide member, along an inner wall of the skirt portion of the outside guide member; the outside guide member and the inside guide member are brought into engagement with each so as to be incapable of sliding, at the position where the distal end of the puncture needle recedes to the inside of the inside guide member; and the engagement between the outside guide member and the inside guide member being released by inserting a mouth portion of a vial into the inside guide member.

[0008]

Here, the engagement between the outside guide member and the inside guide member is attained by: selecting, as the outside guide member, a member which includes an annular projection provided in an inner wall of a distal end of the skirt portion, a plurality of notches formed in a portion of a proximal end side with respect to this annular projection, and a plurality of flexible engaging claws provided in these notches, the plurality of flexible engaging claws inclining toward an inside in a distal end direction; and

selecting, as the inside guide member, a member which has an annular projection provided in an outer wall of its proximal end, a plurality of notches formed in a proximal end portion corresponding to the engaging claws, and a plurality of flexible pushing claws provided in these notches, the plurality of flexible pushing claws inclining toward an inside in a proximal end direction. Therefore, at a position where the tip of the puncture needle recedes into the inside of the inside guide member, the engaging claws engage the proximal end of the inside guide member and the annular projection of the outside guide member engages the annular projection of the inside guide member. By inserting the mouth portion of the vial into the inside guide member, the pushing claws push the engaging claws to the outside, causing the engagement claws to deform to release the engagement between the outside guide member and the inside guide member.

Further, the puncture member may be formed either integrally with or separately from the outside guide member. In order to separately form the puncture member, for example, on an axis of the top surface of the outside guide member, a puncture needle insertion portion having a hole that passes through the top surface is provided, and the puncture member which is provided separately from the outside guide member is inserted into the hole of this puncture needle insertion portion. A plurality of vertical ribs may be provided in an inner wall of the inside guide member to make

it easier for the vial to slide along the inner wall of the inside guide member. Further, a collar that inclines toward the outside in the distal end direction may also be provided in the distal end of the skirt portion of the outside guide member in such a manner that the inside guide portion cannot be gripped during vial insertion (when the inside guide portion is held by hand, the hand gets in the way and it becomes difficult to make the inside guide member slide).

It should be noted that the terms "proximal end" and "distal end" as used in the present invention refer to an upper end and a lower end, respectively, in Fig. 3.

[0009]

[Embodiment Mode of the Invention]

An embodiment of the present invention is explained next using the drawings.

Fig. 1 is a plan view that shows an embodiment of the present invention. Fig. 2 to Fig. 4 are a bottom view, a front view, and a left side view, respectively, of Fig. 1. Fig. 5 is a cross sectional view of Fig. 1 taken along a line X-X. Fig. 6 and Fig. 7 are a left side view of an inside guide member shown in Fig. 1, and a perspective view of main portions thereof, respectively. Further, Fig. 8 is a cross sectional view similar to Fig. 5, showing another embodiment of the present invention, and Fig. 9 are views for explaining how a transfer needle assembly of the present invention is used.

As shown in Figs. 1 to 5, the transfer needle assembly according to the present invention includes a cap-like outside guide member 1, a tubular inside guide member 2, and a puncture member 3. The puncture member 3 is a tubular member having a tip fitting portion 31 at its proximal end and a puncture needle 32 at its distal end. The puncture needle 32 is provided with a gas passage 322 which is provided with an air filter 33 in an opening portion 324 and a liquid passage 321 which communicates with the tip insertion portion 31. Further, the inside guide member 2 is capable of sliding from a position where a distal end of the puncture needle 32 recedes into the inside of the inside guide member 2, to a position where the distal end of the puncture needle 32 projects out to the outside of the inside guide member 2, along an inner wall of the skirt portion 12 of the outside guide member 1. The outside guide member 1 and the inside guide member 2 are engaged with each other so as to be incapable of sliding, at a position where the distal end of the puncture needle 32 recedes to the inside of the inside guide member 2; and the engagement between the outside guide member 1 and the inside guide member 2 is released by inserting a mouth portion of a vial into the inside guide member 2.

[0010]

The outside guide member 1 is a cap-like member that is normally formed by using a flexible resin such as polypropylene, polyethylene, polyester, polyvinyl chloride, or ABS resin. The outside guide

member 1 has a top surface 11 and the skirt portion 12. The inside guide portion 2 is inserted into the skirt portion 12, and the puncture member 3 is provided in the top surface 11, passing through the top surface 11.

When the inside guide member 2 is gripped by hand, the hand gets in the way and it becomes difficult to slide the inside guide member 2. A collar 13 having a funnel shape, for example, which inclines to the outside in a distal end direction may also be provided in the distal end of the skirt portion 12 of the outside guide member 1 in such a manner that the inside guide member 2 is not gripped during vial insertion.

The inside guide member 2 is a tubular member that is formed by using a material similar to that used for the outside guide member 1. The inside guide member 2 has an outer diameter that is slightly smaller than the inner diameter of the skirt portion 12 so that it becomes possible for the inside guide member 2 to slide along an inner wall of the skirt portion 12 of the outside guide member 1.

The outside guide member 1 and the inside guide member 2 are engaged so as to be incapable of sliding with respect to each other before use, at a position where a tip of the puncture needle 32 recedes into the inside of the inside guide member 2. This engagement can be released by inserting an mouth portion 41 of a vial 4 (refer to Fig. 9b) into the inside guide member 2. When the engagement

between the outside guide member 1 and the inside guide member 2 is released, it becomes possible to slide the inside guide member 2 along the inner wall of the skirt portion 12 of the outside guide member 1, from a position where the tip portion of the puncture needle 32 recedes into the inside of the inside guide member 2 to a position where the puncture needle 32 projects to the outside.

[0011]

The engagement between the outside guide member 1 and the inside guide member 2 as described above is, for example, structured as shown in Figs. 5 and 8. That is, in the outside guide member 1, an annular projection 121 is provided in an inner wall of a distal end of the skirt portion 12, a plurality of notches 123 are formed in a portion of the proximal end side with respect to this annular projection 121, and a plurality of flexible engaging claws 122 that incline toward the inside in a distal end direction are provided in these notches 123. In the inside guide member 2, on its proximal end side, an annular projection 21 is provided in an outer wall of its proximal end as shown in Figs. 6 and 7. A plurality of notches 25 are formed in the proximal end portion corresponding to the engaging claws 122, and a plurality of flexible pushing claws 22 that incline toward the inside in a proximal end direction are provided in the notches 25. Before use, at the position where the distal end of the puncture needle 3 recedes into the inside of the inside guide member 2, the engaging claws 122 engage (engage in the collide state)

the proximal end 24 of the inside guide member 2 and the annular projection 121 of the outside guide member 1 engages the annular projection 21 of the inside guide member 2. By inserting the mouth portion 41 of the vial 4 into the inside guide member 2, the pushing claws 22 are deformed to bend outward, and the outwardly bent pushing claws 22 push the engaging claws 122 to the outside, thereby releasing the engagement between the outside guide member 1 and the inside guide member 2. It should be noted that reference numeral 221 denotes a pushing portion of the pushing claw 22. The pushing portion is formed projecting to the outside so as to be situated at a height where it reliably releases the engagement between the engaging claw 122 and the proximal end 24 of the inside guide member 2 when the vial mouth portion 41 is inserted into the inside guide member 2.

A plurality of vertical ribs 23 may also be provided in the inside guide member so that the vial 4 slides more easily along the inner wall of the inside guide member 2.

[0012]

The puncture member 3 may be formed integrally with the outside guide member 1 as shown in Fig. 8, and may also be provided separately from the outside guide member 1 as shown in Fig. 5. When the puncture member 3 is provided separately from the outside guide member 1, a puncture needle insertion portion 14 having a hole 141 that passes through the top surface 11 may be formed on the axis of the top surface 11 of the outside guide member 1 as shown in Fig. 2, for

example. The puncture needle 32 of the puncture portion 3, which is formed separately from the outside guide member 1, may be inserted into the hole 141 of the puncture needle insertion portion 14. It should be noted that an annular groove 142 may also be formed in the hole 141, engaging with an annular projection 323 that is formed in an outer wall of the puncture needle 32 so that the puncture member 3 does not fall off from the puncture needle insertion portion 14 during use.

[0013]

Use of the transfer needle assembly of the present invention is explained next using Fig. 9.

First, a transfer needle assembly TN like that shown in Fig. 5 is prepared (Fig. 9a). The engaging claw 122 of the outside guide member 1 is engaged with the proximal end 24 of the inside guide member 2 at this point (Fig. 9d). Next, the mouth portion 41 of the vial 4 is inserted into the transfer needle assembly TN. The transfer needle assembly TN is pushed forward to a position where the mouth portion 41 of the vial 41 pushes the pushing claw 22 of the inside guide member 2 and deflects the pushing claw 22 to the outside (Fig. 9b). At this point, the engaging claw 122 is pushed on and deflects to the outside by the pushing claw 22 that has deflected to the outside. The engagement between the engaging claw 122 and the proximal end 24 of the inside guide member 2 is thus released (Fig. 9e). When the transfer needle assembly TN is pushed further

forward, a rubber stopper 42 of the mouth portion 41 of the vial is pricked by the puncture needle 32 of the puncture member 3, and the inside of the vial 4 is communicated with the outside through the transfer needle assembly TN (Fig. 9c). If a syringe tip (not shown) is fitted onto the tip fitting portion 31 in this state, a solution or the like filled into the syringe in advance can be injected. Further, a medical liquid after dissolution can be aspirated from within the vial 4 into the syringe.

[0014]

[Effect of the Invention]

As is apparent from the description above, the inside of a vial can be communicated with the outside simply by a hand pushing operation when employing the present invention, and therefore dissolution operations are easy. Further, the needle tip recedes into the inside of the inside guide member before use, and therefore contamination of the needle tip, and injuries caused by the needle tip, can be avoided when performing dissolution operations. Furthermore, the puncture needle can prick right through a center portion of the rubber stopper due to the inside guide member, and therefore liquid leakage during dissolution operations can be prevented.

[Brief Description of the Drawings]

[Fig. 1]

A plan view showing an embodiment of the present invention.

[Fig. 2]

A base view of Fig. 1.

[Fig. 3]

A front view of Fig. 1.

[Fig. 4]

A left side view of Fig. 1.

[Fig. 5]

A cross sectional view of Fig. 1 taken along a line X-X.

[Fig. 6]

A left side view of an inside guide member that is shown in Fig. 1.

[Fig. 7]

A perspective view of main portion of the inside guide member that is shown in Fig. 1.

[Fig. 8]

A cross sectional view that is similar to Fig. 5, showing another embodiment of the present invention.

[Fig. 9]

Views for explaining how a transfer needle assembly according to the present invention is used.

[Description of Symbols]

1 outside guide member

11 top surface

12 skirt portion

121 annular projection

122 engaging claw

123 notch

13 collar

14 puncture needle insertion portion

141 hole

142 annular groove

2 inside guide member

21 annular projection

22 pushing claw

221 pushing portion

23 vertical rib

24 proximal end of inside guide member

25 notch

3 puncture member

31 tip fitting portion

32 puncture needle

321 liquid passage

322 gas passage

323 annular projection

324 opening portion

33 air filter

4 vial

41 mouth portion

42 rubber stopper

TN transfer needle assembly

[Document Name] Abstract

[Summary]

[Object] To provide a transfer needle assembly with which: a dissolution operation can be carried out easily; a contamination of a tip of a needle and an injury by the tip of the needle can be avoided; and a leakage of a liquid during the dissolution operation can be prevented.

[Solving Means] A transfer needle assembly includes: a cap-like outside guide member 1; a tubular inside guide member 2; and a puncture member 3. The puncture member 3 has a tip fitting portion 31 at a proximal end and a puncture needle 32 at a distal end, and is provided with a gas passage 322 that has an air filter 33, and a liquid passage 321 that communicates with the tip insertion portion 31. The inside guide member 2 can slide from a position where a distal end of the puncture needle 32 recedes into the inside of the inside guide member 2, to a position where the distal end of the puncture needle 32 projects out to the outside of the inside guide member 2, along an inner wall of a skirt portion 12 of the outside guide member 1. At the position where the distal end of the puncture needle 32 recedes to the inside of the inside guide member 2, the outside guide member 1 and the inside guide member 2 are engaged together so as to be incapable of sliding, with the engagement between the outside guide member 1 and the inside guide member 2 being released by inserting a mouth portion of a vial into

the inside guide member 2.

[Selected Drawing] Fig. 5

Fig. 1

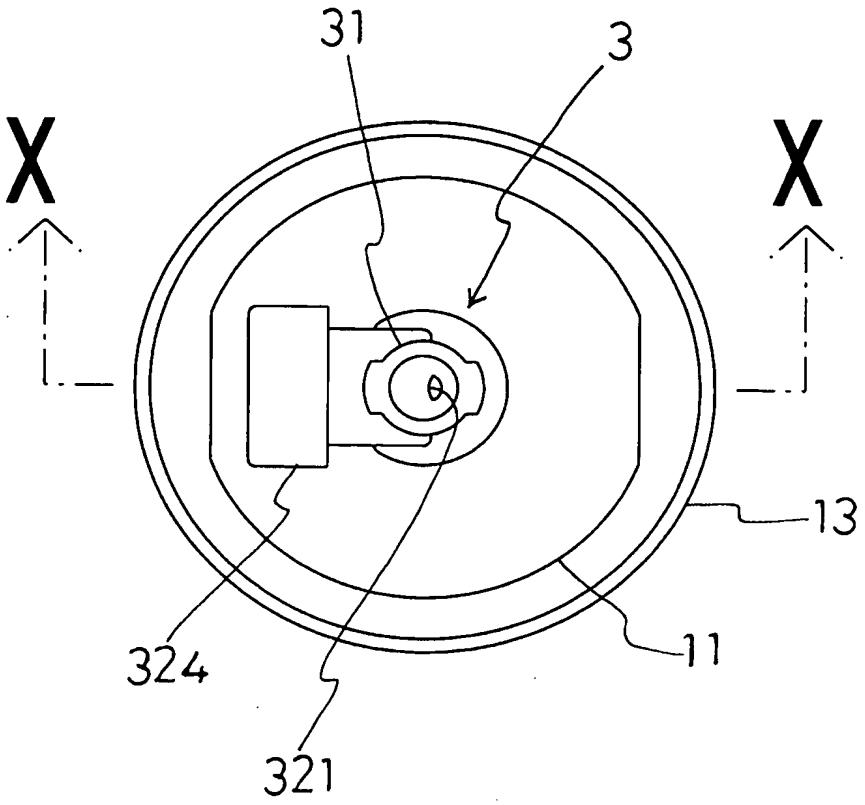


Fig. 2

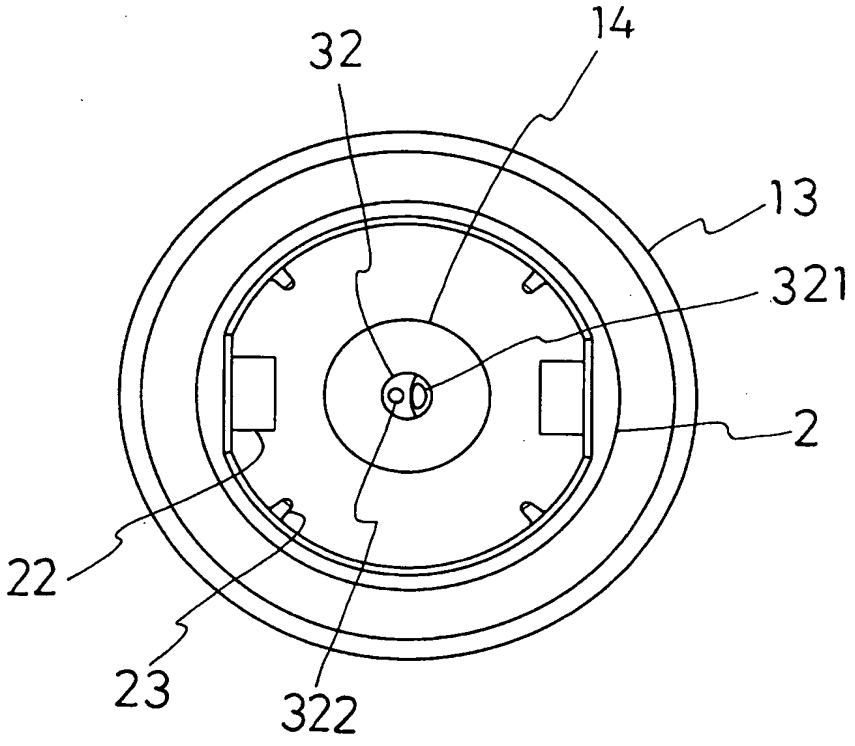


Fig. 3

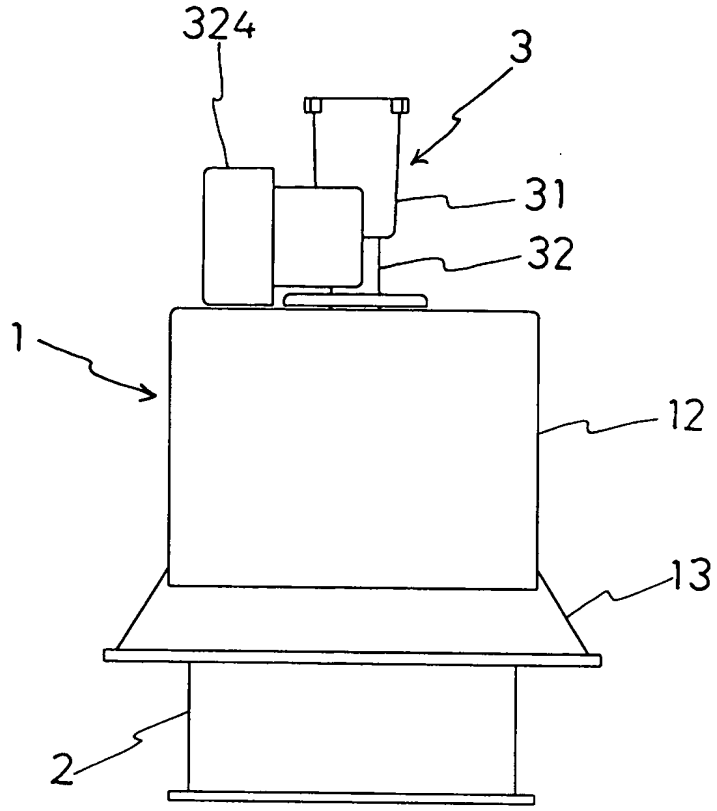


Fig. 4

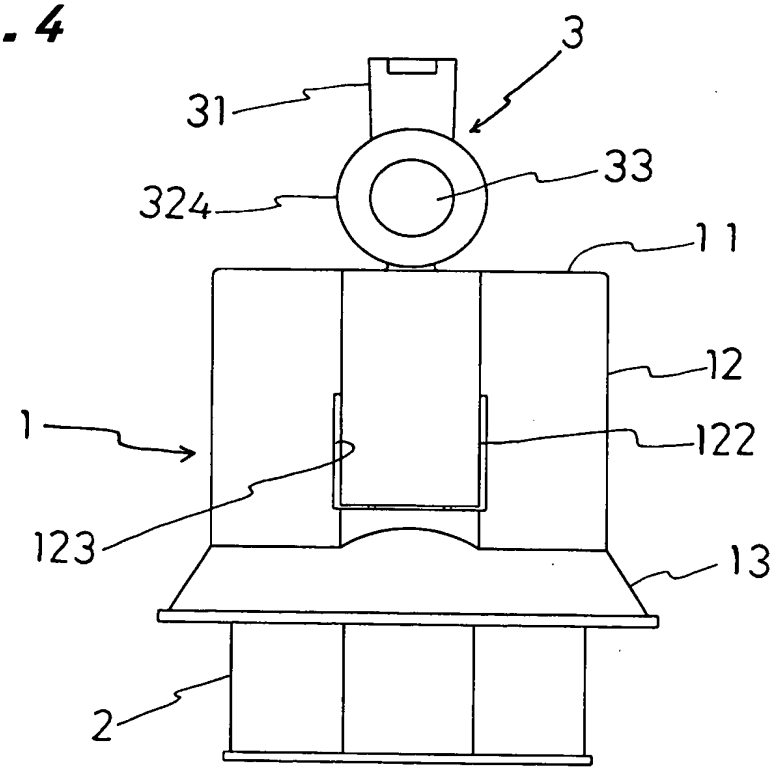
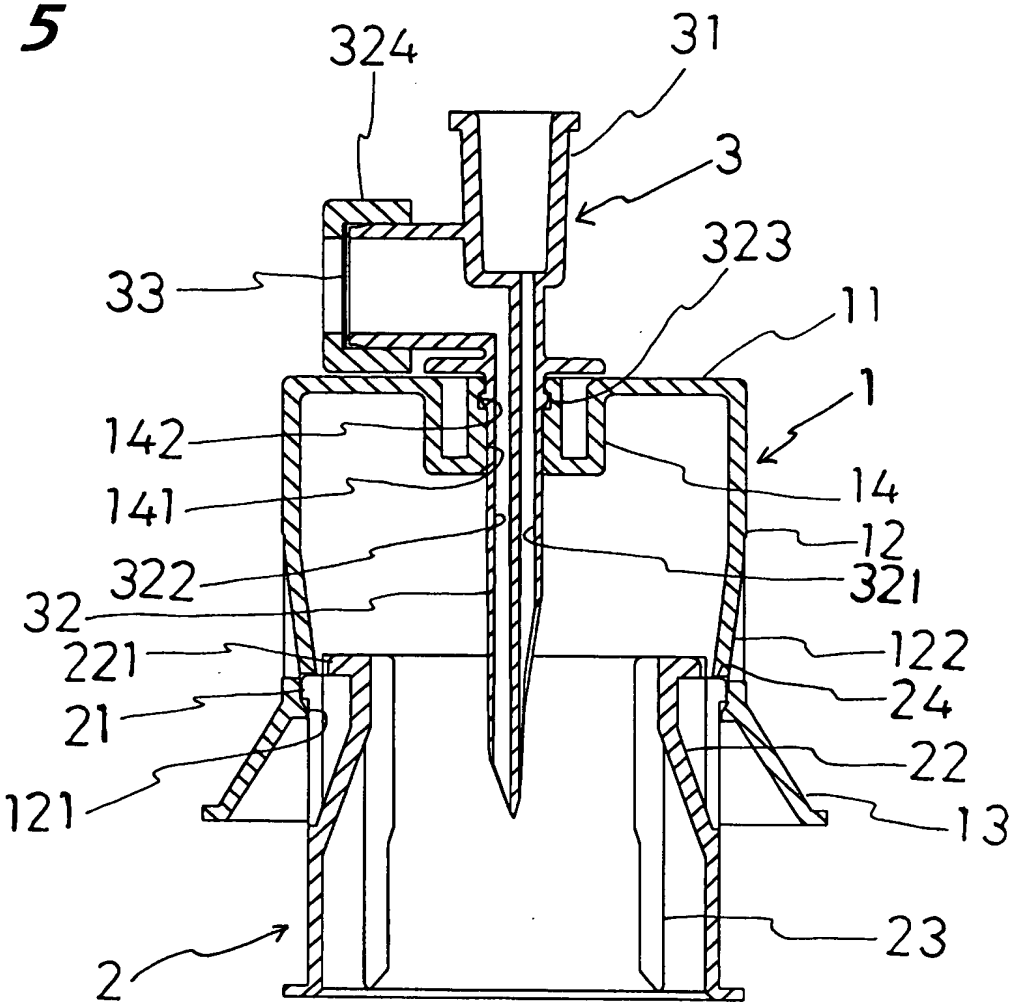


Fig. 5


324
31
3
323
33
11
1
142
14
141
12
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321
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122
221
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21
22
121
13
23
2

Fig. 6

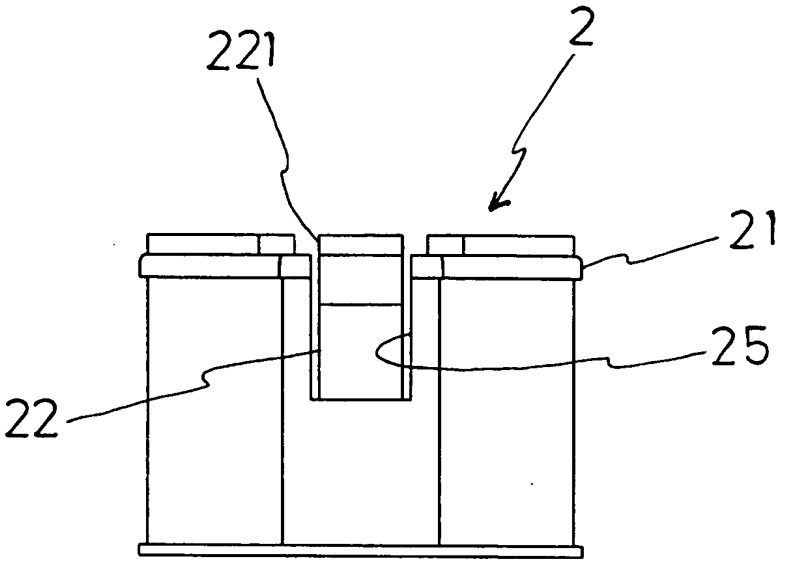

Fig. 7

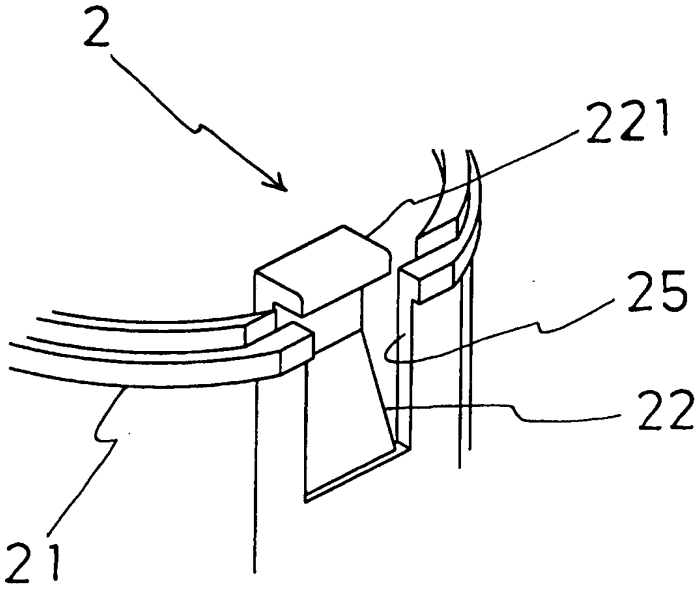

Fig. 8

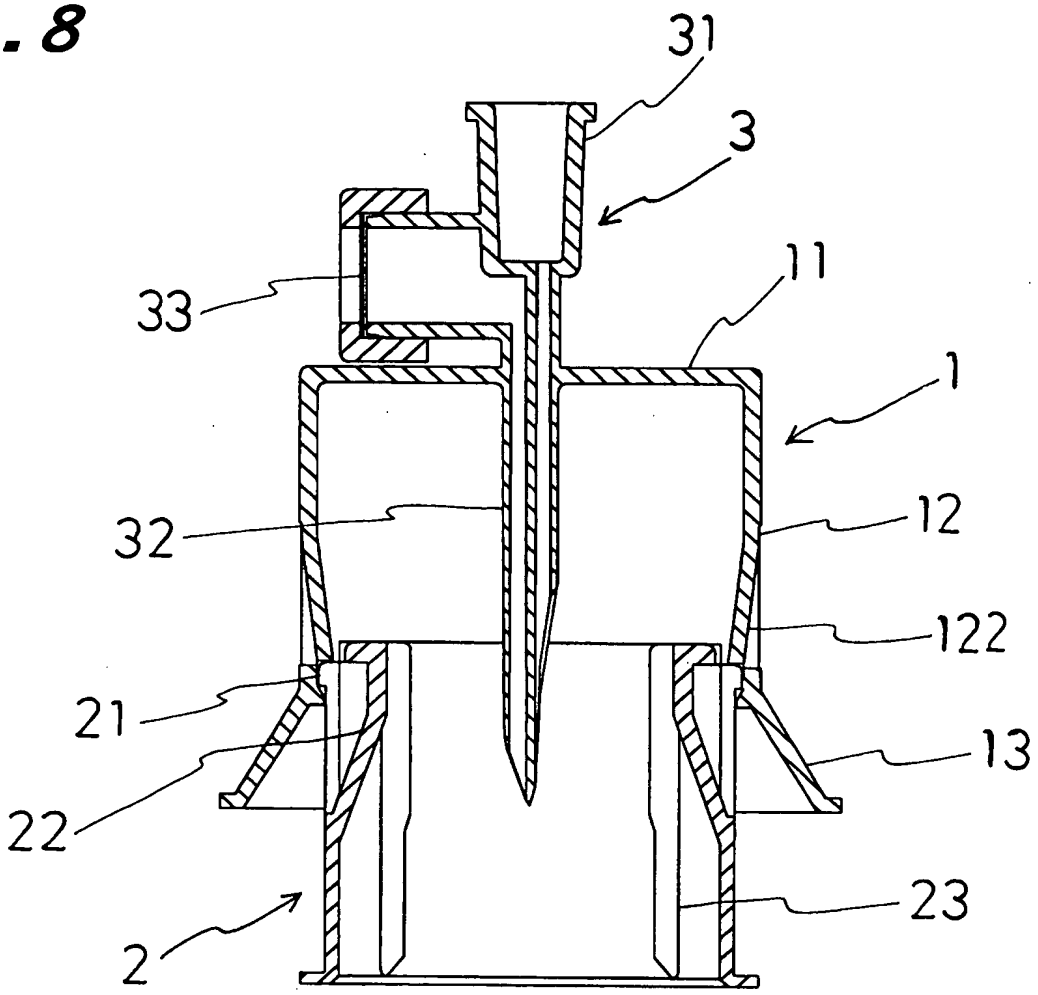

Fig. 9